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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,587	07/29/2003	Kei Roger Aoki	17328CON5	1664

7590 04/10/2006

EXAMINER	
KAM, CHIH MIN	

ART UNIT	PAPER NUMBER
1656	

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DATE MAILED: 04/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/630,587	AOKI ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 January 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31-35,37 and 38* is/are rejected.

7)☒ Claim(s) *36* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 31-38 are pending.

Applicants' request for reconsideration and terminal disclaimers filed on January 27, 2006 are acknowledged. Applicants' response has been fully considered. Thus, claims 31-38 are examined.

Withdrawn Claim Rejections - 35 USC § 102

2. The previous rejection of claims 31-34, 37 and 38 under 35 U.S.C. 102(b) as being anticipated by Borodic *et al.* (WO94/15629), is withdrawn in view of applicants' response at page 5 in the request for reconsideration filed January 27, 2006.

Withdrawn Claim Rejections-Obviousness Type Double Patenting

3. The previous rejection of claims 31-38 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4-5 of U. S. Patent 6,869,610, is withdrawn in view of applicants' submission of terminal disclaimer, and applicants' response at page 4 in the request for reconsideration filed January 27, 2006.

4. The previous rejection of claims 31-38 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 5 and 7-12 of U. S. Patent 6,464,986, is withdrawn in view of applicants' submission of terminal disclaimer, and applicants' response at page 4 in the request for reconsideration filed January 27, 2006.

5. The previous rejection of claims 31-38 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4, 5, 9, 12, 13 and 28-32 of co-pending application 10/630,206, is withdrawn in view of applicants' submission of

terminal disclaimer, and applicants' response at page 4 in the request for reconsideration filed January 27, 2006.

Maintained Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

6. Claims 31-35, 37 and 38 remain rejected under 35 U.S.C. 102(a) as anticipated by Barwood *et al.* (Developmental Medicine & Child Neurology 42, 116-121 (February 2000).

Barwood *et al.* teach using botulinum toxin A (BTX/A) to treat the postoperative pain in children with spastic cerebral palsy (CP), where the pain is often attributed to muscle spasm (abstract). Preoperative intramuscular injection of BTX/A to children with CP reduced postoperative pain, analgesic requirements and complications, as well as facilitated an earlier discharge from hospital (page 117, left column; page 120, right column). For example, five to 10 days before the scheduled date of surgery, the children with CP were injected with effective amount of BTX/A in saline at two sites close to the specific adductor muscles, and equal volumes of normal saline were used for placebo injections, it was found that the BTX/A group had a significant reduction in postoperative pain during their admission and analgesic requirements as compared to placebo group, and the effect has lasted at least 3-6 months (pages 117-120; Table II; claims 31-35, 37 and 38).

Response to Arguments

Applicants indicate a feature of the present invention is treatment of postoperative incisional wound pain, while the Barwood reference teaches the treatment of a postoperative pain attributed to muscle spasms associated with cerebral palsy. A postoperative incisional wound pain is different from a postoperative pain attributed to muscle spasms associated with cerebral palsy. For example, the present specification explains that an incisional wound pain is due to a surgical incision (see page 23, lines 13-20). On the other hand, the postoperative pain referenced by the Barwood reference is due to muscle spasms associated with cerebral palsy (see abstract), and the statement "In children with CP, it is unlikely that incisional pain alone is responsible for the postoperative course experience by many, and it is considered that muscle spasms play a major role" (see page 116, second column). Thus, the Barwood reference is differentiating between a postoperative incisional wound pain and a postoperative pain attributed to muscle spasms associated with cerebral palsy (pages 5-6 of the response).

Applicants' response has been considered, however, the arguments are not found persuasive because of the following reasons. The Barwood reference teaches preoperative intramuscular injection of BTX/A to children with CP reduced postoperative pain and analgesic requirements (see Table II), where the postoperative pain is mainly due to muscle spasms, but it can also be due to incisional wound because the reference indicates BTX/A reduces the amount of analgesics required for the treatment of postoperative pain including incisional pain (see Table II, BTX/A vs. placebo in morphine and codeine requirements) and may have analgesic role in other postoperative situation in the management of children with CP (see page 120, right column). Therefore, the Barwood reference does teach the use of BTX/A in the treatment of

postoperative incisional pain in the patient with CP, which is not different from the claimed method.

The statement in the Barwood (see page 116, second column) merely indicates muscle spasms play a major role in the postoperative pain experienced by children with CP, it does not rule out that postoperative pain is partly due to incisional pain. Regarding the statement in the specification (page 23, lines 13-20),

> "The present invention also includes a method for treating a post-operative pain where the pain is a result of the surgical procedure carried out (i.e. the pain is due, at least in part, to the incisions made)."

which indicates post-operative pain can be partly due to incision pain.

Claim Objection

7. Claim 36 is objected to because the claim is dependent from a rejected claim.

Conclusion

8. Claims 31-35, 37 and 38 are rejected; and claim 36 is objected to.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Patent Examiner

CHIH-MIN KAM
PATENT EXAMINER

CMK
April 6, 2006